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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19-19LI]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Long-term sequela of Rocky Mountain spotted fever (RMSF) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on February 7, 2019 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Long-term sequela of Rocky Mountain spotted fever (RMSF) – New
ICR – National Center for Emerging and Zoonotic Infectious

Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Data collection for this investigation was initiated in July 2018 following OMB approval on 7/22/2018, with a second approval on 11/15/2018 under the Emergency Epidemic Investigations (EEI) Generic ICR (OMB Control Number 0920-1011, exp 1/31/2020). A full OMB package is being submitted to allow for continuation of the project. CDC is seeking three years of OMB approval.

Rocky Mountain spotted fever (RMSF), a life-threatening and rapidly progressive tickborne disease, is caused by infection with the bacterium *Rickettsia rickettsii*. Infection begins with non-specific symptoms like fever, headache, and muscle pain, but when left untreated the bacteria can cause damage to blood vessels throughout the body leading to organ and tissue damage. Delay in recognition and treatment of RMSF can result in irreparable damage leading to amputation of extremities, neurological deficits (such as hearing loss, paralysis, and encephalopathy), and death.

Case series in the peer-reviewed literature document long term sequelae (LTS) from RMSF in anywhere from 3-55% of cases, yet characterization of the long-term impacts is still not well understood, and only a handful of studies have examined them in

detail. Results of neurologic damage caused during acute RMSF illness may include symptoms ranging from paresthesia, insomnia and behavioral concerns to loss of hearing, motor or language dysfunction, and chronic pain.

This study will gather information related to neurologic sequela following RMSF illness. Information for this study will come from three sources: medical charts, patient interviews, and neurological exams with a cognitive/developmental assessment for children. Resulting data will provide information to healthcare providers, patients, and policy makers about the long term consequences of severe RMSF, including time to recovery, self-reported impact to daily function, and will look to identify risk factors during acute illness which may be associated with long term impairment.

There is no cost to respondents other than the time to participate. Total estimated burden is 42 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
General Public	Patient screening questionnaire	84	1	10/60
	Neurological exam form	42	1	40/60

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